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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/877,340	06/08/2001	Thomas Bock	4420.000600	1031

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NIXON & VANDERHYE, PC
1100 N GLEBE ROAD
8TH FLOOR
ARLINGTON, VA 22201-4714

EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/877,340	BOCK ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *1-6 and 10-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *sequence letter*.

DETAILED ACTION

Amendment filed on 01/20/2002 has been acknowledged. Claim 2 has been amended. Claims 1-35 are pending.

Sequence requirements

This application contains sequence disclosure in line5 of page 3 that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Full compliance with the sequence rules is required in response to this Office Action. A complete response to this office action should include both compliance with the sequence rules and a response to the Office Action set forth below. Failure to fully comply with **both** these requirements in the time period set forth in this office action will be held non-responsive.

Election/Restrictions

1. Applicant's election with traverse of Group III, claim 7 in Paper No. 20 is acknowledged. The traversal is on the ground(s) that upon allowance of group III, the office will have to search at least group IV and V. This traverse is not persuasive since Group II is not currently allowable. Further, while searches for plural inventions often overlap, there is no reason to expect the searches to be coextensive.

2. However, during the examination, groups III-V are rejoined due to the overlapping prior art come across in the searches.

3. The requirement for the restriction of other groups that applicants do not raise any argument is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

5. Claims 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 7-9 are unclear in that the metes and bounds of "an HBV agent" are not defined. The claims are interpreted in light of the specification; however, the specification does not teach what the definition of " an HBV agent" is. Please clarify.

7. Regarding claim 9, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

9. Claims 7 and 9 are rejected under 35 U.S.C. 102(a) as being anticipated by Kioko et al. (J. Clini. Invest. 1999, Vol. 103, No. 12, pp. 1635-1640).

10. Kioko et al. teach a method for detecting an agent that may exhibit an anti-HBV replication activity. The method comprises constructing different plasmids encoding different HBV mutants and transfecting Huh-7 cells with one of the plasmids construct that include a full-length HBV wild-type DNA or M552I, M552V, and L528M/M552V mutants of HBV DNAs. Then they add an anti-viral agent, such as lobucavir, adefovir, nevirapine and penciclovir into the transfected Huh-7 cell lines respectively to test whether the viral replication are changed (See section of Method on pages 1636). They also teach to use southern blot hybridization method for detecting the inhibition of HBV expressions by the agents (See Section of Discussion on page 1638-1639). Therefore the claimed invention is anticipated by the cited reference.

11. Claims 7-9 are rejected under 35 U.S.C. 102(a) as being anticipated by Delaney et al. (Antimicrobial Agents and Chemotherapy 1999, Vol. 43, no. 8, pp. 2017-2026).

12. Delaney et al. teach a method for detecting an agent that may exhibit an anti-HBV replication activity. The method comprises generating a HepG2 cell lie that express replicating HBV DNA by using a baculovirus construct that comprises a1.3-unit length replication-competent HBV genome, and then adding a potential anti-HBV agent lamivudine (3TC) into the cell culture to see the inhibitory effect assessed by nucleic acid hybridization assays (Both Northern and southern blots) and hepatitis B surface antigen (HBsAg) radioimmunoassay. The transfected HepG2 cell becomes a cell line that expresses HBV replication intermediates and extracelluar HBV DNA particle (See section of MATERIALS AND METHODS on page 2018). Because the baculovirus vector is a genetic construct that is used for delivering a gene, the claims 7-9 are all anticipated by the cited reference.

13. Claim 9 is rejected under 35 U.S.C. 102(a) as being anticipated by Ying et al. (J. Viral Hepatology, 2000, Vol. 7, pp. 161-165).

14. Ying et al. teach a method for testing whether some nucleoside analogues have an activity against HBV infection, especially for the one having a laevudine-resistant HBV variant M550V mutation. The method comprising to contacting the HepAD38 and hepAD97 cells that are stably tansfected with either a cDNA copy of the wild-type pregenomic RNA or with cDNA containing M550V mutation and detecting the viral replication at the presence or absence of testing agent. The assay for detecting the viral replication is quantitative PCR (See entire document, especially, page 163). The test compounds include lobucavir, lamivudine and penciclovir. Therefore the claimed invention is anticipated by the cited reference.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Doong et al. (Proc. Natl. Acd. Sci. USA 1991, Vol. 88, pp. 8495-8499).

17. Doong et al. teach a method for detecting an agent that may exhibit an anti-HBV replication activity. The method comprises treating HepG2 cells, which is transfected with a plasmid containing HBV DNA and expresses a replicating HBV viral DNA (2.2.15 cells) in the presence and absence of an anti-viral agent, such as D4C and 3'FddC, respectively. The testing assays include Southern blot and Northern blot (See section of Method on pages 8495 and Results on pages 8496-8497 and Fig. 2 on page 8497). Therefore, the claimed invention is anticipated by the cited reference.

18. Claims 7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Ueda et al. (Virol. 1989, Vol. 169, pp. 213-216).

19. Ueda et al. teach a method for detecting an agent against HBV replication in vitro. The method comprises constructing a DNA construct encoding the HBV genome (Fig. 1 on page 213) and transfecting the construct into a mammalian cell line (HB 611), establishing the cell line that constitutively expresses the replicating HBV genome as DANE-like particle released into the culture medium, contacting the cell line with a testing agent and detecting the viral DNA expression by southern blot assay in the presence and absence of anti-HBV candidate agent (See entire document, especially Fig. 2 on page214 and Table 1 on page 215). Therefore, the claimed invention is anticipated by the cited reference.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li May 20, 2004

James C. Housel 6/1/04
JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Notice to Comply	Application No.	Applicant(s)	
	Examiner	Art Unit	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: See instruction in office Action

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
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